DECLARATION

FILING OF TRANSLATION OF PRIORITY DOCUMENT

As a translator of the English language publicly appointed and generally sworn-in by the president of the *Landgericht München I* (Munich Regional Court I), I, Ursula Dentler, of Josephsburgstr. 7, 81673 Munich, Federal Republic of Germany, do hereby certify that I am conversant with the English and German languages and am a competent translator thereof and that the attached document is a true and correct translation into the English language of the priority document 198 31 798.0 filed in the name of Mandorlo Investment GmbH on July 15, 1998.

Signed this twenty-fifth day of April 2001

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(vv)

Skin and tissue care and/or treatment preparation

The invention relates to a skin and tissue care and/or treatment preparation. In particular, the invention relates to a preparation for care, protection and prevention of tissue-damaging manifestations and effects and for the treatment of skin and tissue, wherein said preparation comprises at least one salt selected from alkali and alkaline earth metal salts and other minerals and is characterized in that it contains at least one amino acid and zinc oxide and/or an inorganic peroxide. Optionally, the inventive preparation can additionally contain an adstringent, a binding and adhesive agent, a humectant, an ethereal oil, tego-betaine, secondary plant substances such as epigallocatechines, unsaturated fatty acids, liposomes, vitamins, trace elements and antifungal and/or antimicrobial components.

Natural nutrients are essential for the health of cells and body. They serve to maintain and regenerate the skin as well as to stimulate metabolism and oxygen supply of the cells. The extensive significance of nutrient supply becomes also more and more important in the field of skin care, cosmetic and dermatology. Hormonal modifications, predisposition, an unbalanced and wrong diet and unhealthy habits, especially smoking and lack of exercise, lead to typical manifestations of the skin, such as tissue modifications, tissue deformations and cellular metabolic disturbances. A well-aimed supply of nutrients harmonizes metabolism and thus results in a natural, physiological equilibrium of the cells.

It is generally known that vitamins, minerals and trace elements are indispensable to the nutrient supply of the skin. Proteins which are built up of amino acids are an important building component for cells and endogenous active substances, such as enzymes and certain hormones. Polyunsaturated fatty acids, secondary plant substances, such as flavonoids and epigallocatechines, and liposomes in general are becoming more and more important for health and fitness. Vitamins, minerals and trace elements, polyunsaturated fatty acids and bioactive plant substances such as flavonoids are essential regulators in the metabolism and protective nutrients for the health of the skin.

Vitamins are essential nutritional components which, for the normal functions of heterotrophic organisms, have to be supplied more or less obligatorily and in correspondence to the needs, since they are only available either from external sources or under the influence of milieu factors (e.g. intestinal flora). Their specific biocatalytic effect is based on the replacement of the active groups of enzymes which are subject to metabolical consumption. From science it is for example known that B-type vitamins contribute to the intermediary metabolism as coenzymes and that vitamins C, E and β-carotene mainly function as antioxidants. Deficiencies resulting from insufficient supply or resorption, disorders of the intestinal flora or of metabolism, antivitamin-effect or increased consumption lead to hypovitaminosis and avitaminosis.

Furthermore, minerals and trace elements are essential regulators in the metabolism. Zinc, magnesium and the B-type vitamins are high-performance elements as they activate enzymes and thus allow the metabolism of carbohydrates, fats and protein substances. Silicon has a favorable effect on stability and maintenance of the skin. Furthermore, it is scientifically undisputed that zinc has an essential function in the immune system and in the metabolism of the skin.

Polyunsaturated fatty acids contain linolic acid, and α- and γ-linolenic acid, which are important starting substances for biologically active regulators in the metabolism, such as eicosanoids and prostaglandins, and which ensure a healthy equilibrium in the metabolism. Currently, eicosanoids and prostaglandins, also referred to as tissue hormones, are being intensively examined by scientists with regard to their health stabilizing effect. The favorable influence of the polyunsaturated fatty acids on the healthy skin function as well as on inflammatory

processes is known. Furthermore, it is known that polyunsaturated fatty acids of the type of the ω-3-(eicosapentaenoic acid, α-linolenic acid) and ω-6-fatty acids (linolic acid, γ-linolenic acid) have favorable effects e.g. on neurodermatitis and psoriasis as well as regeneration processes induced by physical strain during exercise. The importance of the so-called secondary plant substances, in the special branch of science also referred to as bioactive plant substances, for health is now being examined as well. Bioflavonoids, which effectively support the effects of vitamin C with regard to the power of resistance, vascular walls and connective tissue also count among these natural plant substances. Furthermore, it is known that bioflavonoids have antioxidant properties and that they thus synergistically complement the effect of the vitamins C, E and β-carotene.

With regard to biosynthesis aspects, amino acids are divided into essential, semi-essential and non-essential amino acids. In addition to their function as building blocks for proteins, amino acids are precursors of biologically effective compounds. Amino acids are i.a. described in L. Stryer, Biochemie, Spektrum Akademischer Verlag, Oxford, 1994 and in Römpp Lexikon Chemie, editor J. Falbe and M. Regitz, keyword "amino acids", Thieme Verlag, 1996 and bibliographic references cited therein.

Liposomes are particles surrounded by single or multi-layered phospholipid double membranes which can be loaded with hydrophilic pharmaceutical molecules in the inner, aqueous phase. By using them as pharmaceutical carriers, a selective local enrichment of active substances and a delayed release of active substances can be achieved.

Numerous preparations for treating and preventing mycotic, microbic, pathologic and other tissue-damaging manifestations and effects, tissue modifications, tissue deformations and cellular metabolic disturbance and other forms of damage to human tissue are commercially available. There are, for example, various therapeutic approaches for treating skin and connective tissue problems. The success of many of these preparations is, however, questionable, as these preparations are unable to reach the damaged cells and/or to act in the damaged cells. Furthermore, many of the products that are commercially available do not take the active mechanism discovered by scientists into account in which the cell is remineralized in a natural way and metabolism is stimulated so that the natural

inner pressure of the cell is reestablished, the cell volume is normalized and fat and waste substances are effectively displaced and secreted.

An object of the present invention is to provide a skin and tissue care and/or treatment preparation which distinguishes itself by a quick effect, excellent tolerance, a broad field of application and particularly intense deep action. In particular, the preparation is supposed to be applicable for care, protection, prevention of tissue-damaging manifestations and effects and for the treatment of skin and tissue. The preparation according to the invention is supposed to take into account research results concerning the diffusion of ions through ion channels into the intracellular space and microcirculation in the cell.

An object of the present invention is solved by the provision of a composition comprising the following components:

(a) at least one salt selected from alkali and alkaline earth metal salts and other minerals,
characterized in that it contains
(b) at least one amino acid, and
(c) zinc oxide and/or an inorganic peroxide.

In preferred embodiments the inventive preparation can additionally comprise, each independently of the other, at least one adstringent agent, a humectant, an ethereal oil, tego-betaine, secondary plant substances such as flavonoids and epigallocatechines, unsaturated fatty acids, liposomes, vitamins, trace elements and antifungal and antimicrobial components. Furthermore, it can comprise usual carriers and adjuvants as well as binding and adhesive agents and usual solvents. In a preferred embodiment the preparation of the present invention is topically used through direct application at the site of action.

The preparation of the present invention takes into account new research results concerning the diffusion of ions through ion channels into the intracellular space. Hereby ions of mineral salts penetrate through the upper skin layers deep into the cell interior of hypoderm, connective tissue and fat cells. The inventive preparation uses i.a. the principle of ion exchange between cell interior and cell exterior using high osmotic pressure which is created by the combination of active substances of the preparation. In this process, however, the amino acids, which help the ions to

more effectively overcome the natural barriers of the cell membranes through so-called ion channels to reach the cell interior, which is the actual site of action, play an important role.

Alkali and alkaline earth metal salts and other minerals are essential regulators in the metabolism. In the present invention all known alkali and alkaline earth metal salts and minerals, which can also be present as trace elements, can be used. Preferred representatives of the group of alkali and alkaline earth metal salts and minerals that can be used in the present invention are sodium, potassium, magnesium, calcium, silicon, zinc, manganese, copper, iron, fluorine, chlorine, bromine, iodine and phosphorus. Preferred trace elements are accidental trace elements, such as silver, gold, aluminum, barium, bismuth, cadmium, chrome, nickel, lead, tin, titanium and vanadium, and essential trace elements, such as chrome, cobalt, copper, fluorine, iron, iodine, manganese, molybdenum and selenium, which are present in, for example, enzymes, chromoproteins and hormones as constituents. The amount of the alkali and alkaline earth metal salts and other minerals in the inventive preparation is preferably 20 to 90 percent by weight, more preferably 25 to 85 percent by weight, based on the sum of all components in the preparation, depending on the desired osmotic effect. The alkali and alkaline earth metal salts and the other minerals are added in the form of usual salt compounds or organic compounds. For example, sodium, potassium and magnesium are preferably added in the form of their chloride salts, sodium and calcium in the form of phosphates.

The adstringent agents which are optionally usable in the present invention comprise usual compounds for this purpose. Tannin, hamamelis, rhubarb, rhatany, and salvia are preferably used as adstringent. The amount of the adstringent agents in the inventive preparation is preferably 0 to 30 percent by weight, more preferably 1 to 25 percent by weight, based on the sum of all components in the preparation. The adstringent agents are preferably added in a pure form.

In the present invention usual humectants can optionally be used. Preferred humectants are glycerin, aloe vera, collagen, desamidocollagen, collagen hydrolysates, elastin hydrolysates, hyalomucco solution, fibrostimulin, PN 73, Q 10, water, aloe barbadensis gel, camelia sinensis extract, hedera helix extract, matricaria (camomile recutita) oil and butylene glycol. The amount of the humectants in the inventive preparation is preferably 0 to 70 percent by weight,

more preferably 5 to 50 percent by weight, based on the sum of all components in the preparation.

Furthermore, the preparation of the present invention can optionally comprise usual ethereal oils. Preferred ethereal oils are oils of camomile, lavender, rosemary, camphor, mountain-pine, mint, tea tree and eucalyptus. The amount of the ethereal oils in the preparation of the present invention is preferably 0 to 70 percent by weight, more preferably 5 to 55 percent by weight, based on the sum of all components in the preparation. The ethereal oils are preferably added in a pure form or in the form of extracts or cold-drawn and warm-drawn oils.

The preparation of the present invention can contain all known amino acids and amino acid derivatives. Preferred amino acids and amino acid derivatives are leucine, isoleucine, valine, tryptophan, arginine, lysin, asparagine and glutamine. The amino acids and amino acid derivatives can be used solely or in the form of mixtures. The amount of amino acids and amino acid derivatives in the preparation of the present invention is preferably 1 to 40 percent by weight, more preferably 5 to 30 percent by weight, based on the sum of all components in the preparation. The amino acids and their derivatives are preferably added in a pure form.

The preparations of the present invention are furthermore characterized by the presence of zinc oxide and/or an inorganic peroxide. As inorganic peroxides preferably zinc peroxide, sodium peroxide, potassium peroxide, calcium peroxide or magnesium peroxide are used. Zinc oxide and/or an inorganic peroxide, for example, can be used to regulate the osmotic pressure. Surprisingly, the combination of amino acids with zinc oxide and/or an inorganic peroxide has a particularly good effect, compared to the use of magnesium peroxide alone. The total amount of zinc oxide and inorganic peroxide in the preparation of the present invention is preferably 1 to 50 percent by weight, more preferably 5 to 40 percent by weight, based on the sum of all components in the preparation. The amount of inorganic peroxide, if applied topically, should preferably not be larger than 10 percent by weight, more preferably not larger than 6 percent by weight, and, if applied internally, not larger than 20 percent by weight, more preferably not larger than 15 percent by weight. Zinc oxide and inorganic peroxide are preferably added in a pure form.

Optionally, tego-betaine can additionally be present in the preparation of the present invention. The amount of tego-betaine in the inventive preparation is preferably 0 to 25 percent by weight, more preferably 1 to 20 percent by weight and most preferably 5 to 10 percent by weight based on the sum of all components in the preparation.

Optionally, the preparation of the present invention can contain all known bioactive plant substances, also called secondary plant substances. The secondary plant substances used in the present invention particularly comprise carotinoids, phytosterols, saponins, polyphenols, flavonoids, terpenes, phytoestrogens, sulfides, phytin acid and dietary fiber. Of the above-mentioned bioactive plant substances particularly the polyphenols, the flavonoids and the bioflavonoids are used in the present invention. Bioflavonoids of natural sources are especially preferred in the inventive preparation. The bioactive plant substances can be present in the preferred embodiments of the preparation in a preferred amount of 0 to 75 percent by weight, more preferably 2 to 50 percent by weight, based on the sum of all components in the preparation. Preferred natural sources for the bioflavonoids are vegetables, such as pulses, carrots, tomatoes, broccoli and paprika, corn, citrus fruits, green and black tea, grapes, etc. The bioactive plant substances are preferably added in the form of extracts.

Optionally, all known unsaturated fatty acids can additionally be used in the preparation of the present invention. Preferably unsaturated fatty acids that are included in vegetable and animal oils (such as fish oil) are used. Polyunsaturated fatty acids from vegetable sources are essential precursors of important regulators of metabolism (eicosanoids and prostaglandines). The amount of unsaturated fatty acids in the inventive preparation is preferably 0 to 70 percent by weight, more preferably 2 to 45 percent by weight, based on the sum of all components in the preparation. Examples for preferred purely vegetable sources of unsaturated fatty acids are evening primrose oil, flax oil, olive oil, wheat germ oil, soy oil, sunflower oil, borage oil, pumpkin seed oil and oil of the seeds of the redcurrant. The unsaturated fatty acids are preferably added in the form of cold-drawn oils.

Optionally, the preparation of the present invention can furthermore additionally contain usual liposomes, lecithin and lipodermine. Liposomes are important, as they control the release of vitamin A and vitamin E. That way these vitamins are accessible over a longer period of time. The amount of liposomes, lecithin or

lipodermine in the inventive preparation is preferably 0 to 30 percent by weight, more preferably 2 to 20 percent by weight, based on the sum of all components in the preparation.

Optionally, the preparation of the present invention can additionally comprise epigallocatechines, preferably recovered from green tea. Through epigallocatechines the aging of the cells can be delayed. Furthermore, they are important as cosubstances and serve to support the effect of micronutrients, such as vitamins. The amount of the epigallocatechines in the preparation is preferably 0 to 60 percent by weight, more preferably 2 to 30 percent by weight, based on the sum of all components in the preparation. The epigallocatechines are preferably added in a pure form or as extracts.

Optionally, the preparation of the present invention can additionally comprise all known representatives of vitamins and provitamins. Particularly vitamins A, those of the B-complex, C, D and E and β-carotene are preferably used in the preparation. The amount of the vitamins in the preparation of the present invention is preferably 0 to 75 percent by weight, more preferably 5 to 50 percent by weight, based on the sum of all components in the preparation. The vitamins are added both in a natural form as extracts and in a synthetic form (e.g. B-vitamins), whereby differences in the effect of the vitamins are not linked with this fact.

Optionally, the preparation of the present invention can additionally comprise antifungal and antimicrobial components. Antibiotics, bacteriostatics, corticosteroids, cortisones, econazol nitrate, dexametasone, hydroxy benzoate, etc. can be added to the inventive preparation. The amount of the antifungal and antimicrobial components in the preparation is preferably 0 to 60 percent by weight and most preferably 2 to 30 percent by weight, based on the sum of all components in the preparation.

Optionally, the preparation of the present invention can comprise all known adjuvants, additives and carrier substances, the usual binding and adhesive agents and solvents. Preferred examples are milk fat, unhydrogenated, partly hydrogenated or hydrogenated soy fat, soy oil, walnut butter, glycerin, gelatin, pectin, lecithin, β-carotenes, sorbitol solution, iron oxide, titanium dioxide, dyes, fats, waxes, emulgators, silicones, polyethylenes, polysorbitones, (meth)acryl compounds, talcum, dragantum, starch, vaseline, dextrose, saccharin, paraffins,

acids, preservatives and fragrances. Pectin is preferably used as binding and adhesive agent. Usual amounts of the above-mentioned substances and agents are used, e.g. pectin up to an amount of 10 percent by weight, based on the sum of all components in the preparation.

The preparation of the present invention can be prepared in the usual manner known to every person skilled in the art, for example by combining the active ingredients with suitable, non-toxic, inert, pharmaceutically acceptable solid or liquid carrier materials and optionally the usual additives, adjuvants and solvents to a galenic form of administration. Methods for manufacturing galenic forms of administration, such as ointments and creams, are for example described in H. Sucker, B. Fuchs, P. Speiser, "Pharmazeutische Technologie", 2nd edition (1991), Georg Thieme Verlag Stuttgart; R. Voigt, "Lehrbuch der pharmazeutischen Technologie", Thieme Verlag, 1976. For the preparation of the present invention all known forms of application are possible. Preferred forms of application are cream, ointment, paste, emulsion, lotion, solution, gel, powder, spray, gelatin, foam and the like. Forms of application for internal application are for example capsules, tablets, coated tablets, drinking solutions and injection solutions, for example for hypodermal injections. A depot form as form of application is possible as well.

In principle, all known modes of application are possible for the preparation of the present invention. The most preferred one is the topical application, for example effected by applying a corresponding form of application to the skin, e.g. by applying, rubbing on, rubbing gently in, spraying on, etc. Application is also possible in the form of ointment bandages or hypodermal injections. The preparation of the present invention can be applied once or several times a day and both over short and long periods of time. However, the daily dose and the frequency of the application per day depends on the recipe of the individual inventive preparation.

Depending on the recipe, the preparations of the present invention are suitable as food supplement, cosmetic or pharmaceutical composition, preferably as topical cosmetic or as topical pharmaceutical composition to be applied on the skin and tissue of mammals, and are for example used for the care, protection and prevention of tissue-damaging manifestations and effects and for the treatment of skin and tissue. Depending on their recipe, they are in a preferred embodiment

particularly applicable to all skin irritations, cellulitis, acne, herpes, psoriasis, neurodermatitis, ozone damage, burns, caustic burns, cellular metabolic disturbances and other modifications with accumulation of tissue fluid, fat and other cellular products and cellular catabolites, such as thickenings, edemas, hematomas, and are furthermore applicable to, for example, hemorrhoids, rheumatism, arthrosis, and skin cancer. The preparation can also be applied to mucous membranes, e.g. in the digestive system.

The present invention is further illustrated by an example.

Example

A preparation according to the invention having the following components was prepared in the usual manner:

Zinc oxide	8 wt.-%
Sodium peroxide	3 wt.-%
Sodium phosphate	10 wt.-%
Calcium phosphate	6 wt.-%
Calcium chloride	5 wt.-%
Arginine	7 wt.-%
Leucine	8 wt.-%
Asparagine	5.5 wt.-%
Valine	2 wt.-%
Hamamelis	1 wt.-%
Tannin	3 wt.-%
Pectin	1 wt.-%
Tego-betaine	2 wt.-%
Vitamin A	1 wt.-%
Vitamin E	1.5 wt.-%
β-carotene	0.5 wt.-%
Collagen	1.5 wt.-%
Aloe Vera	2 wt.-%
Olive oil	2 wt.-%
Carotinoids	2 wt.-%
Gelatin	1 wt.-%
Liposomes	2 wt.-%

Purified water ad	100 wt.-%

The composition of the above example was applied to one leg of probands. To the other leg control substances (placebo substances; control leg) were applied. The results of the examinations can be summarized as follows:

As acute reaction of the above inventive recipe an increase of microcirculation was found. After about 50 minutes a significant improvement of microcirculation was observed, whereby a maximum increase was reached after about 100 minutes. The significant effective phase was observed after about 120 minutes. On the control leg no changes in microcirculation were observed. As a further reaction caused by the application of the inventive recipe, a reduction of the fat layer on the treated leg could be observed, while there was no modification on the control leg. Through these examinations it was shown that the inventive preparation can significantly improve microcirculation and reduce the fat layer.

In further applications of recipes which are part of the invention, significantly positive effects regarding aging, elasticity, moisture, wrinkling and tightening of the skin were observed.

Claims

1. Preparation comprising the following components:
   (a) at least one salt selected from alkali metal salts, alkaline earth metal salts and other minerals,
   characterized in that it contains
   (b) at least one amino acid, and
   (c) zinc oxide and/or an inorganic peroxide.

2. Preparation according to claim 1, characterized in that it additionally comprises tego-betaine.

3. Preparation according to claim 1 or 2, characterized in that it additionally comprises at least one secondary plant substance and/or at least one epigallocatechine.

4. Preparation according to any one of claims 1 to 3, characterized in that it additionally comprises at least one unsaturated fatty acid and/or at least one trace element.

5. Preparation according to any one of claims 1 to 4, characterized in that it additionally comprises at least one liposome and/or at least one vitamin.

6. Preparation according to any one of claims 1 to 5, characterized in that it additionally comprises at least one adstringent agent and/or at least one humectant and/or at least one ethereal oil.

7. Preparation according to any one of claims 1 to 6, characterized in that it additionally comprises antifungal and/or antimicrobial components.

8. Preparation according to any one of claims 1 to 7, characterized in that it additionally comprises at least one component selected from carrier substances, adjuvants, additives, binding agents, adhesive agents and solvents.

9. Preparation according to any one of claims 1 to 8, comprising the following components:

(a) 20 to 90 wt.-% of a salt, selected from alkali metal salts, alkaline earth metal salts and other minerals,

characterized in that contains

(b) 1 to 40 wt.-% of an amino acid, and

(c) a total amount of zinc oxide and inorganic peroxide of 1 to 50 wt.-%, based on the sum of all components in the preparation.

10. Preparation according to any one of the claims 1 to 9, comprising the following components:

(a) at least one metal salt selected from sodium, potassium, magnesium, calcium, silicon, zinc, manganese, copper, iron, fluorine, chlorine, bromine, iodine and phosphorus,

characterized in that it contains

(b) at least one amino acid or amino acid derivative selected from leucine, isoleucine, valine, tryptophan, arginine, lysin, asparagine and glutamine, and

(c) zinc oxide and/or an inorganic peroxide.

11. Preparation according to any one of claims 1 to 10, characterized in that the inorganic peroxide is zinc peroxide, sodium peroxide, potassium peroxide, calcium peroxide or magnesium peroxide.

12. Use of a preparation according to any one of claims 1 to 11 for topic application.

13. Use of a preparation according to claim 12 as a cosmetic.

14. Use of a preparation according to claim 12 as a pharmaceutical composition.

15. Use of a preparation according to any one of claims 1 to 11 as a pharmaceutical composition.

16. Use of a preparation according to any one of claims 1 to 11 as a food supplement.

Abstract

Skin and tissue care and/or treatment preparation

The invention relates to a skin and tissue care and/or treatment preparation. In particular, the invention relates to a preparation for care, protection and prevention of tissue-damaging manifestations and effects and for the treatment of skin and tissue, wherein said preparation comprises at least one salt selected from alkali and alkaline earth metal salts and other minerals and is characterized in that it contains at least one amino acid and zinc oxide and/or an inorganic peroxide. Optionally, the inventive preparation can additionally contain an adstringent, a binding and adhesive agent, a humectant, an ethereal oil, tego-betaine, secondary plant substances such as epigallocatechines, unsaturated fatty acids, liposomes, vitamins, trace elements and antifungal and/or antimicrobial components.